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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

PETTIS *et al.*

Application No. 10/028,988 ✓

Filed: December 28, 2001

For: Method and Devices for  
Administration of Substances into the  
Intradermal Layer of Skin for Systemic  
Absorption

Group Art Unit: N/A

Examiner: N/A

Atty. Docket No. P-4901P5

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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

This is an Information Disclosure Statement submitted under 37 C.F.R. § 1.56 and 1.97.

In order to comply with the duty of disclosure pursuant to 37 C.F.R. § 1.56, submitted herewith is a form listing the documents cited in the International Search report of International Application Nos. PCT/US01/20763 (AC, AD, AG, AK, BE); PCT/US01/20782 (AB, BH, AR, AA); and PCT/US01/50440 (AU, AO, AZ, BI, BJ). The relevance of these documents is indicated in the International Search Report. The remaining references (AE-AF, AH-AJ, AL-AN, AP-AQ, AS-AT, AV-AY, BA-BD, BF-BG and BK-BR) are being submitted for the Examiner's consideration. An English language translation has been provided for document BL so no further statement of relevance need be given.

The submission of this Information Disclosure Statement and the accompanying form PTO/SB/08A should not be construed as an admission that the cited references are prior art to the subject application.

It is respectfully requested that the Examiner consider the cited documents and make them of record.

Date: December 2, 2002

Respectfully submitted,



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**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
P-4901P5

In Re Application Of: **PETTIS, et al.**

Serial No.  
10/028,988

Filing Date  
12/28/2001

Examiner  
N/A

Group Art Unit  
N/A

Title: **Methods and Devices for Administration of Substances into the Intradermal Layer of Skin for Systemic Absorption**



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Address to:  
Assistant Commissioner for Patents  
Washington, D.C. 20231

**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:
- ☐ the statement specified in 37 CFR 1.97(e);
- OR**
- ☐ the fee set forth in 37 CFR 1.17(p).

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
P-4901P5

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Filing Date  
12/28/2001

Examiner  
N/A

Group Art Unit  
N/A

Methods and Devices for Administration of Substances into the Intradermal Layer of Skin for Systemic



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**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

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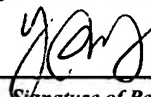
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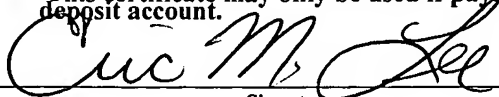
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Signature

Dated: December 2, 2002

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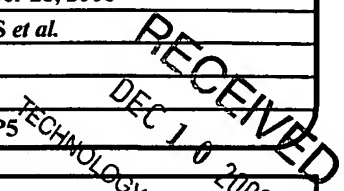
# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

## Complete if Known

Application Number	10/028,988
Filing Date	December 28, 2001
First Named Inventor	PETTIS et al.
Group Art Unit	N/A
Examiner Name	N/A
Attorney Docket Number	P-4901P5

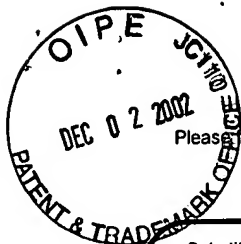


## U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	AA	2,619,962		Rosenthal	12/02/1952	
	AB	3,814,097		Ganderton et al.	06/04/1974	
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## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sub>6</sub>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	AY	CA	2 349 431		Canada	05/25/2000		
	AZ	EP	1 086 718	A1	Europe	03/28/2001		
	BA	EP	1 086 719	A1	Europe	03/28/2001		
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	BC	EP	1 092 444	A1	Europe	04/18/2001		
	BD	WO	96/17648		PCT	06/13/1996		
	BE	WO	96/37155		PCT	11/28/1996		
	BF	WO	96/37256		PCT	11/28/1996		
	BG	WO	99/43350		PCT	09/02/1999		
	BH	WO	99/64580		PCT	12/16/1999		
	BI	WO	00/67647		PCT	11/16/2000		
	BJ	WO	00/74763	A2	PCT	12/14/2000		
	BK	WO	02/11669	A2	PCT	02/14/2002		



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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

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Application Number	10/028,988
Filing Date	December 28, 2001
First Named Inventor	PETTIS <i>et al.</i>
Group Art Unit	N/A
Examiner Name	N/A
Attorney Docket Number	P-4901PS

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### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BL	E. AUTRET et al., Therapie 1991, 46 : 5-8.	
	BM	BRESSOLLE et al., "A Weibull Distribution Model for Intradermal Administration of Cefazidime", Journal of Pharmaceutical Sciences, Vol. 82, No. 11, November 1993, pps. 1175-1178.	
	BN	HENRY et al., "Microfabricated Microneedles: A Novel Approach to Transdermal Drug Delivery", Journal of Pharmaceutical Sciences, Vol. 87, No. 8, August 1998, pps. 922-925.	
	BO	KAUSHIK et al., "Transdermal Protein Delivery Using Microfabricated Microneedles", Oct/Nov 1999 (1 page).	
	BP	BURKOTH et al., "Transdermal and Transmucosal Powered Drug Delivery", Critical Review™ in Therapeutic Drug Carrier Systems, 16 (4), (1999), pps. 331-384.	
	BQ	MCALLISTER et al., "Three-Dimensional Hollow Microneedle and Microtube Arrays", Conference: Solid-State Sensors and Actuators Transducers-Conference, 1999; 10 <sup>th</sup> ; Vol. 12, pp 1098-1103.	
	BR	MCALLISTER et al., "Solid and Hollow Microneedles for Transdermal Protein Delivery", Proceed. Int'l. Symp. Control. Rel. Bioact. Mater., 26 (Revised July 1999) Controlled Release Society, Inc. pp. 192-193	

Examiner Signature		Date Considered	
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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2. under 37 CFR 1.97(b) or (c)
3. Information Disclosure Statement by Applicant (Form PTO/SB 08A)
4. Information Disclosure Statement
5. Cited References

Docket No.: P-4901P5

Filing Date: 12/28/2001 Serial No.: 10 / 028,988

Date Mailed: 12/2/2002

Applicant(s) Pettis, et al.

Method and Devices for Administration of Substances into the

Title: Intradermal layer of skin for Systemic Absorption Att'y: EML

Fee: \$0.00

Charged to Deposit Account 02-1666